

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

Short Title: Operation

Rule Numbers: §291.33

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, clarify and update the section to be consistent with other sections; require documentation of a consultation with a prescriber regarding a prescription; change the days supply for alternate labeling from 34 day supply or 100 dosage units whichever is less to a 90 day supply; and require automated checking devices to be fully automated.

Background: Board staff presents these amendments to update the Class A rules regarding the operation of a pharmacy.

The Board reviewed and voted to propose the amendments during the February 5, 2013, meeting. The proposed amendments were published in the March 8, 2013, issue of the *Texas Register* at 38 *TexReg* 1637.



CHAPTER 291. PHARMACIES
SUBCHAPTER B. COMMUNITY PHARMACY
(CLASS A)

22 TAC §291.33

The Texas State Board of Pharmacy proposes amendments to §291.33 concerning Operational Standards. The amendments, if adopted, clarify and update the section to be consistent with other sections; require documentation of a consultation with a prescriber regarding a prescription; and change the days supply for alternate labeling from 34-day supply or 100 dosage units whichever is less to a 90-day supply.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to update and clarify the Class A rules regarding the operation of a pharmacy. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8008. Comments must be received by 5:00 p.m., April 30, 2013.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.33. Operational Standards.

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application).

(2) - (3) (No change.)

(4) A Class A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within ten days of the change, following the procedures as specified in §291.3 of this title.

(5) A Class A pharmacy shall notify the board in writing within ten days of closing, following the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).

(6) - (7) (No change.)

(8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of Subchapter C of this chapter (relating to [§291.51 of this title (relating to Purpose), §291.52 of this title (relating to Definitions), §291.53 of this title (relating to Personnel), §291.54 of this title (relating to Operational Standards), and §291.55 of this title (relating to Records), contained in] Nuclear Pharmacy (Class B)), to the extent such sections are applicable to the operation of the pharmacy.

(9) A Class A [~~community~~] pharmacy engaged in the compounding of non-sterile pharmaceuticals shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(10) A Class A [~~community~~] pharmacy engaged in the compounding of sterile pharmaceuticals shall comply with the provisions of §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(11) A Class A [~~Community~~] pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(12) Class A [~~Community~~] pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Centralized Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(b) Environment.

(1) General requirements.

(A) - (B) (No change.)

(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall be:

(I) [~~be~~] easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

(II) [~~be~~] designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) (No change.)

(D) (No change.)

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The [~~the~~] temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, service animals [~~guide dogs~~] accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(G) (No change.)

(2) Security.

(A) - (D) (No change.)

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such policies [policies] and procedures may include quarterly audits of controlled substances commonly abused or diverted; perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy; opening and closing procedures; product storage and placement; and central management oversight.

(3) (No change.)

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent, information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) - (iv) (No change.)

(v) techniques for self-monitoring of drug therapy;

(vi) - (viii) (No change.)

(B) Such communication shall be:

(i) [shall be] provided with each new prescription drug order;

(ii) [shall be] provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) [shall be] communicated orally in person unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) [shall be] documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) - (IV) (No change.)

(v) [shall be] reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information.

(I) Written information must be in plain language designed for the patient [consumer] and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman.

(II) When a compounded preparation [product] is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) - (IV) (No change.)

(C) - (D) (No change.)

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable.

(i) - (ii) (No change.)

(iii) A Class A pharmacy shall make available for use by the public a current or updated patient prescription drug

information reference text or leaflets [edition of the United States Pharmacopeia Dispensing Information, Volume II (Advice to the Patient); or another source of such information] designed for the patient [consumer].

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable.

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) - (v) (No change.)

(G) - (I) (No change.)

(2) Pharmaceutical care services.

(A) Drug regimen review.

(i) (No change.)

(ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences as specified in subparagraph (C) of this paragraph.

(iii) (No change.)

(iv) Prior to dispensing, any [Any] questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.

(B) Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practices Act;

(ii) - (v) (No change.)

(C) Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph the pharmacist shall document on the hard-copy or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information:

(i) date the prescriber was consulted;

(ii) name of the person communicating the prescriber's instructions;

(iii) any applicable information pertaining to the consultation; and

(iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation if on the information is recorded on the hard-copy prescription.

(3) - (4) (No change.)

(5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This paragraph does not apply to generic substitution. For generic substitution, see the requirements of paragraph (3) of this subsection.

(A) - (B) (No change.)

(C) The provisions of this paragraph do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of this state if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must maintain a copy of the formulary including a list of the practitioners that have agreed to the formulary and the signature of these practitioners.

(6) (No change.)

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) - (v) (No change.)

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) [(vi)] name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(viii) [(vii)] instructions for use that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(ix) [(viii)] quantity dispensed;

(x) [(ix)] appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) [(x)] if the prescription is for a Schedules II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) [(xi)] if the pharmacist has selected a generically equivalent drug pursuant to the provisions of the Act, Chapter 562 [Chapters 562 and 563], the statement "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;

[(xii)] the name of the advanced practice nurse or physician assistant and the name of the supervising physician, if the prescription is carried out or signed by an advanced practice nurse or physician assistant in compliance with Subtitle B, Chapter 157, Occupations Code;

[(xiii)] the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code, and the name of the supervising physician;

(xiii) [(xiv)] the name and strength of the actual drug product dispensed that is printed in an easily readable font size

comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic name

and name of the manufacturer or distributor of such generic drug. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products or non-sterile compounded drug preparations [preparations] having no brand name, the principal active ingredients shall be indicated on the label.)

(II) Except as provided in clause (xii) [(xi)] of this subparagraph, the brand name of the prescribed drug shall not appear on the prescription container label unless it is the drug product actually dispensed.

(xiv) [(xv)] if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) [(xvi)] either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient written information containing the information as specified in subparagraph (A) of this paragraph in an easily readable font size comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) (No change.)

(ii) no more than a 90-day supply [34-day supply or 100 dosage units, whichever is less,] is dispensed at one time;

(iii) - (iv) (No change.)

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) - (-d-) (No change.)

(-e-) name of the prescribing practitioner or [and], if applicable, the name of the advanced practice nurse, [or] physician assistant, or pharmacist who signed the prescription drug order;

(II) [effective June 1, 2010,] if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) (No change.)

(8) (No change.)

(d) (No change.)

(e) Library. A reference library shall be maintained which includes the following in hard-copy or electronic format:

(1) (No change.)

(2) at least one current or updated reference from each of the following categories:

(A) a patient prescription drug information reference text or leaflets which are designed for the patient and must be available to the patient; [patient information;]

~~[(i) United States Pharmacopeia Dispensing Information, Volume H (Advice to the Patient); or]~~

~~[(ii) a reference text or information leaflets which provide patient information;]~~

(B) ~~[drug interactions;]~~ a reference text on drug interactions[, such as Drug Interaction Facts]. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(C) a general information reference text, such as:

(i) (No change.)

~~[(ii) United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);]~~

~~[(ii) [(iii)] Clinical Pharmacology;~~

~~[(iii) [(iv)] American Hospital Formulary Service with current supplements; or~~

~~[(iv) [(v)] Remington's Pharmaceutical Sciences;~~
and

(3) (No change.)

(f) (No change.)

(g) Prepackaging of drugs.

(1) (No change.)

(2) The label of a prepackaged unit shall indicate:

(A) - (B) (No change.)

(C) facility's beyond use date [~~expiration date~~]; and

(D) (No change.)

(3) Records of prepackaging shall be maintained to show:

(A) - (D) (No change.)

(E) manufacturer's expiration date;

(F) - (J) (No change.)

(4) (No change.)

(h) Customized patient medication packages.

(1) (No change.)

~~[(2) Definition: A patient med-pak is a package prepared by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med-pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.]~~

(2) ~~[(3)]~~ Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

(viii) the name, address, and telephone number of the pharmacy;

(ix) the initials or an identification code of the dispensing pharmacist;

(x) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xi) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(xii) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply [~~34-day supply or 100 dosage units, whichever is less;~~] is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) name of the patient; and

(-c-) name and strength of each drug product

dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner of

each drug product, or the pharmacist [and if applicable, the name of the advanced practice nurse or physician assistant] who signed the prescription drug order;

(II) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) for each drug product sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(3) [(4)] Labeling. The patient med-pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med-pak.

(4) [(5)] Packaging. In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med-pak shall comply with official packaging standards. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(5) [(6)] Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient med-pak, to take into account any applicable compendial requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each

container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(6) [(7)] Recordkeeping. In addition to any individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

(A) the name and address of the patient;

(B) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(C) the name of the manufacturer or distributor and lot number for each drug product contained therein;

(D) information identifying or describing the design, characteristics, or specifications of the patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for the patient;

(E) the date of preparation of the patient med-pak and the beyond-use date that was assigned;

(F) any special labeling instructions; and

(G) the initials or an identification code of the dispensing pharmacist.

(7) [(8)] The patient med-pak label is not required to include the initials or identification code of the dispensing pharmacist as specified in paragraph (2)[(3)](A) of this subsection if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(i) Automated devices and systems.

(1) Automated compounding or counting devices. If a pharmacy uses automated compounding or counting devices:

(A) (No change.)

(B) the devices may be loaded with bulk or unlabeled drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(C) (No change.)

(D) records of loading bulk or unlabeled drugs into an automated compounding or counting device shall be maintained to show:

(i) - (iii) (No change.)

(iv) manufacturer's expiration date;

(v) - (vii) (No change.)

(E) the automated compounding or counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her signature to the record as specified in subparagraph (D) of this paragraph.

(2) Automated pharmacy dispensing systems.

(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:

(i) (No change.)

(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The

pharmacy shall make the results of such testing available to the board [Board] upon request; and

(iii) (No change.)

(B) (No change.)

(C) Policies and procedures of operation.

(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall [establish requirements for operation of the automated pharmacy dispensing system and shall describe policies and procedures that]:

~~[(I)]~~ include a description of the policies and procedures of operation;

~~[(I)]~~ [(H)] provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;

~~[(II)]~~ [(HH)] provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;

~~[(III)]~~ [(IV)] require prior to use, that a pharmacist checks, verifies, and documents that the automated pharmacy dispensing system has been accurately filled each time the system is stocked;

~~[(IV)]~~ [(V)] provide for an accountability record to be maintained which documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

~~[(V)]~~ [(VH)] require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

~~[(VI)]~~ [(VH)] establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) (No change.)

(D) Recovery Plan. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

(i) (No change.)

(ii) procedures for response when an automated pharmacy dispensing system is experiencing downtime; and

(iii) procedures for the maintenance and testing of the written plan for recovery; and

~~[(iv)]~~ procedures for notification of the Board, each patient of the pharmacy, and other appropriate agencies whenever an automated pharmacy dispensing system experiences downtime for more than two days of operation or a period of time which significantly limits the pharmacy's ability to provide pharmacy services;

(E) [(3)] Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D)[(b)(2)] of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery

to the patient to ensure that the prescription is dispensed accurately as prescribed.

~~[(i)]~~ [(A)] This final check shall be considered accomplished if:

~~[(I)]~~ [(i)] a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

~~[(II)]~~ [(ii)] the following checks are conducted by a pharmacist:

~~[-a-]~~ [(H)] if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (C)(i)(III) of this paragraph [paragraph (2)(C)(i)(IV) of this subsection]; and

~~[-b-]~~ [(H)] a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system.

~~[(ii)]~~ [(B)] If the final check is accomplished as specified in clause (i)(II) of this subparagraph [subparagraph (A)(ii) of this paragraph], the following additional requirements must be met.

~~[(I)]~~ [(i)] The dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced.

~~[(II)]~~ [(ii)] The pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraphs (A) and (B) of this paragraph [paragraph (2)(A) and (B) of this subsection].

~~[(III)]~~ [(iii)] The automated pharmacy dispensing system documents and maintains:

~~[-a-]~~ [(H)] the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph [subparagraph (A)(ii) of this paragraph]; and

~~[-b-]~~ [(H)] the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, or pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process.

~~[(IV)]~~ [(iv)] The pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every six months as specified in subparagraph (B) of this paragraph [paragraph (2)(B) of this subsection].

(3) [(4)] Automated checking device.

~~[(A)]~~ For the purpose of this subsection, an automated checking device is a fully automated device which confirms, after dispensing but prior to delivery to the patient, that the correct drug and strength has been labeled with the correct label for the correct patient.

(A) [(B)] For the purpose of §291.32(c)(2)(D)[(b)(2)] of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided:

(i) a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed by a pharmacist:

(I) the prepackaged drug used to fill the order is checked by a pharmacist who verifies that the drug is labeled and packaged accurately; and

(II) a pharmacist checks the accuracy of each original or new prescription drug order.

(ii) the prescription is dispensed, labeled, and made ready for delivery to the patient in compliance with Class A (Community) Pharmacy rules; and

(iii) prior to delivery to the patient:

(I) the automated checking device confirms that the correct drug and strength has been labeled with the correct label for the correct patient; and

(II) a pharmacist performs all other duties required to ensure that the prescription has been dispensed safely and accurately as prescribed.

(B) [(C)] If the final check is accomplished as specified in subparagraph (A) [(B)] of this paragraph, the following additional requirements must be met.

(i) The pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient.

(ii) The pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A) [(B)](i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who perform any other portion of the dispensing process.

(iii) The pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly.

(4) [(5)] Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent when the pharmacy is open or when the pharmacy is closed as specified in subsection (b)(3)(B)(iii) of this section, provided:

(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(26) of this title (relating to Definitions);

(B) the automated storage and distribution device may not be used to deliver a controlled substance;

(C) drugs stored in the automated storage and distribution device are stored at proper temperatures;

(D) the patient or patient's agent is given the option to use the system;

(E) the patient or patient's agent has access to a pharmacist for questions regarding the prescription at the pharmacy where the automated storage and distribution device is located, by a telephone available at the pharmacy that connects directly to another pharmacy, or by a telephone available at the pharmacy and a posted telephone number to reach another pharmacy;

(F) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accu-

rately. The pharmacy shall make the results of such testing available to the board upon request;

(H) the automated storage and distribution device may be loaded with previously verified prescriptions only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(I) the pharmacy will make the automated storage and distribution device available for inspection by the board;

(J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

(K) the automated storage and distribution device is secure from access and removal of prescription drug orders by unauthorized individuals;

(L) the automated storage and distribution device has adequate security system to prevent unauthorized access and to maintain patient confidentiality; and

(M) the automated storage and distribution device records a digital image of the individual accessing the device to pick-up a prescription and such record is maintained by the pharmacy for two years.

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 25, 2013.

TRD-201300857

Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

Earliest possible date of adoption: April 7, 2013

For further information, please call: (512) 305-8028



22 TAC §291.34

The Texas State Board of Pharmacy proposes amendments to §291.34 concerning Records. The amendments, if adopted, clarify and update the section to be consistent with other sections of this title and DPS and DEA laws/rules; require documentation of a consultation with a prescriber regarding a prescription; add rules regarding auto-refill programs; and update the rules regarding prescription transfers including no longer allowing interns to transfer prescriptions and specifying that the transfer must be confirmed by each pharmacist.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be to clarify and update the Class A rules regarding the records of a pharmacy. There is no fiscal impact for individuals, small or large businesses, or to other entities which are required to comply with this section.

April 8, 2013

Allison Benz, RPh, MS
Texas State Board of Pharmacy
William P. Hobby Building
333 Guadalupe Street, Suite 3-600
Austin, TX 78701-3942

RE: Comments to Proposed Rules for Adoption

Dear Ms. Benz:

On behalf of HEB, I appreciate the opportunity to submit comments regarding the proposed new rules under §291.33 (Class A Pharmacy Operational Standards) and §291.34 (Class A Pharmacy Records).

H-E-B currently operates 231 pharmacies in the state of Texas and employs over 700 pharmacists, 1400 registered pharmacy technicians and pharmacy technician trainees, and 400 non-registered individuals. Our pharmacies provide prescription services along with other healthcare services such as immunizations, medication therapy management, disease state management, and health screenings to the citizens of Texas.

§291.33 Operational Standards

(iv) **Prior to dispensing, any** [Any] questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained **as specified in subparagraph (C) of this paragraph.**

I wish to commend the Board for taking an active role dictating that all questionable prescriptions, as part of the Drug Regimen Review process, must be clarified and verified accordingly prior to dispensing. This requirement will mitigate the potential for possible medication errors when the prescription is unclear or has contraindications from the beginning in addition to increasing the level of patient safety in our pharmacies.

§291.34 Records

(F) Auto-Refill Programs.

(iii) Prescription refills for controlled substances may not be dispensed by an auto-refill program.

Recognizing the current epidemic of prescription drug abuse, the complete prohibition of controlled substances for auto-refill programs may not serve in a patient's best interest. There are several controlled substances which patients must utilize on a monthly basis which do not carry the same scrutiny as others (for example, patients who take Phenobarbital for seizure control or Lyrica for neuropathic pain control). Although the above-mentioned items are Schedule IV controlled substances, the abuse potential is relatively minimal when compared to high-profile items such as hydrocodone or alprazolam. We believe the decision to add a controlled substance medication to an auto-refill program should not be prohibited but rather be up to the professional judgment of the pharmacist.

(g) Transfer of prescription drug order information. For the purpose of initial or refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements.

(3) The transfer is communicated directly between pharmacists orally by telephone or via facsimile or as authorized in paragraph (9)(E) of this subsection.

(ii) the name of the pharmacist receiving the prescription drug order information

(iii) the name of the pharmacist transferring the prescription drug order information

I appreciate the Board and its willingness to promote patient safety as it relates to the transfers of prescription information. Such proposals above, however, do not include the "pharmacist intern" as an individual who is authorized to transfer prescriptions or receive prescription transfers. Such exclusion would not allow the intern to prepare for his/her full responsibilities as a Registered Pharmacist as it pertains to transfer of prescriptions. We can completely understand the safety concerns during the transfer process when there is an intern on the transferring end and the receiving end. One possible solution would be to dictate that at least one pharmacy employee, during the prescription transfer process, must be a pharmacist.

Thank you for the consideration of our comments.

Please do not hesitate to contact me with any questions, concerns, or further assistance.

Respectfully,



Doug Read, Pharm.D.
Director of Pharmacy Compliance and Regulatory Affairs
H-E-B Pharmacy
3481 Fredericksburg Rd, Suite #2
San Antonio, TX 78201



COALITION FOR NURSES IN ADVANCED PRACTICE

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(512) 694-8349 • www.cnaptexas.org

April 30, 2013

Ms. Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
Delivery via Fax to (512)305-8008

Re: Rule 291.33 (c)(7)(A)(xii) and (c)(7)(D)(v)(I)(-e-) amendments proposed on March 8 3013.

Dear Allison:

The Coalition for Nurses in Advanced Practice (CNAP) supports the amendments to paragraph (c)(7)(A)(xii) and subparagraph (c)(7)(D)(v)(I)(-e-) that the TSBP proposed on March 8th. CNAP agrees the name of the practitioner or pharmacist who signed the prescription should be the only name that appears on the prescription label.

The current labeling rule that requires the dispensing pharmacist to include both the name of the advanced practice nurse (APN) who prescribed the drug and the APN's delegating physician creates confusion for patients. Many patients are not familiar with the APN's delegating physician and certainly did not see that physician when the medication was prescribed. In addition, lack of space on prescription labels and software programs that only allow entering one prescriber can make it difficult for pharmacists to comply with the current rule. Therefore, CNAP thinks these rule amendments, as proposed, will be positive for patients, practitioners and pharmacists.

Thank you for considering this comment. Please do not hesitate to contact me if you have any questions about the comment, or if I may help in clarifying issues involving APNs in the future.

Sincerely,

Lynda Woolbert, MSN, RN, PNP
CNAP Regulatory Consultant
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(512) 750-3747

Cc: Kathy Hutto
Trish Conradt
Jennifer Fontana
CNAP Board